K072978

CONFIDENTIAL

JAN 17 2008

XI. 510(k) Summary

Submitter: Mr. Eugenio Miceli, QA Manager, Micerium SpA, Via Marconi, 83, 16030 Avegno (GE), Italy. Phone: 39 0185 7885 880.

I. Classification Name and Number: Bracket adhesive resin and tooth conditioner (DYH 872.3750)

II. Common/Usual Name: Adhesive for luting ceramic and metal orthodontic brackets.

III. Proprietary Name: Tender Ortho Bond - Ena Bond – Ena Etch

IV. Registration No.: Foreign, in process

V. "ISO 4049:2000 Dentistry – Polymer – Based Filling, Restorative and Luting materials".

VI. Premarket Notification truthful and accurate statement

VII. Description of the Device: Adhesive system, light curable both with halogen and LED Light, for brackets cementation. The accessories contact tissue for less than 1 hour and therefore are exempt from 510(k) requirements and are described only generally.

VIII. Labels and Labeling: Labels of the Tender Ortho Bond, Ena Bond and Ena Etch and instructions for use are provided.

IX. Substantial Equivalence: The Tender Ortho Bond system is substantially equivalent to other composite systems currently on the market used for direct and indirect restorations by dentist and dental technicians. A list of these is provided.

Tender Ortho Bond
The material is the bonding agent for brackets to the teeth.
The composition of Tender Ortho Bond the equivalent products are monomer resins (methacrylates) and starting agents to initiate the polymerisation.

Ena Bond tooth conditioner
The material is applied on the tooth surface after etching and is the bonding agent between the tooth and the composite material (Tender Ortho Bond).
The composition of the products are volatile solvents, matrix oligomers and bonding agents. Most of the equivalent products are very similar. Only the kind of solvent is different in some products.
Ena Bond is used after etching the tooth. Ena Etch is an etching gel 37% phosphoric

acid similar to all the other existing etching gel available in the market for the etching of tooth.

Ena Bond SE tooth conditioner
Ena Bond SE is a two-component system (primer+bond) without fluoride, Transbond Plus SE is a one component system with fluoride.

IX.1 Risk to Health

Potential adverse affects and complications common to composite materials include:

1. Allergy to one of the ingredients
2. No / incomplete hold to the hard teeth substance
3. Leakage creation / danger of secondary caries
4. Irritant for eye and skin

cytotoxicity tests appears in appendix III

X. Indications for Use. Adhesive for luting ceramic and metal orthodontic brackets.

(End of Summary)

We have made every effort to provide the data required for the Center for Devices and Radiological Health (CDRH) to make a substantial equivalence determination on the Tender Ortho Bond – Ena Bond.
The "ISO 4049:2000 Dentistry – Polymer – Based Filling, Restorative and Luting materials" issued September 13th, 2000 and more general documents on preparation of a 510(k) were followed. Your prompt consideration of this premarket notification -510(k) submission will be sincerely appreciated.

If we can provide further clarification or information, please call me or Ms Carla Tazzer (Quality Control) at +39 0185 7887 870 or send a fax at +39 0185 78 87 970 or e-mail to quality@micerium.it

Sincerely yours,

Eugenio Miceli
QA Manager.

MICERIUM S.p.A.
Via G. Marconi, 83 - 16030 AVEGNO (GE)
Partita IVA 01199870104
Tel. 0185-7887870 Fax 0185-7887970

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2008

Dr. Eugenio Miceli
Quality Assurance Manager
MICERIUM S.p.A.
Via Marconi, 83
Avegno, Genoa,
ITALY 16030

Re: K072978
Trade/Device Name: Tender Ortho Bond – Ena Bond – Ena Etch
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: December 14, 2007
Received: December 31, 2007

Dear Dr. Miceli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072978

Device Name: Tender Ortho Bond – Ena Bond – Ena Etch

Indications for Use:

Adhesive for luting ceramic and metal orthodontic brackets

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K072978